

### **REMARKS**

Assignee and the undersigned attorney thank Examiner Barrett for his review of this patent application. Claims 1-101, 111-115, 131-134, 136, 137, 140-142, and 144-181 have been withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected species. Reconsideration of claims 102-110, 116-130, 135, 138, 139, and 143 is respectfully requested.

### **Information Disclosure Statement**

Submitted herewith is a supplemental information disclosure statement citing Harkess et al. with all required information, and, in accordance with 37 CFR §§ 1.97(c) and 1.17(p), a check for \$180.00 is also enclosed. Assignee requests that the Examiner please consider this reference before mailing a reply to this Response to Office Action.

### **Objection to and Amendments to the Specification**

The Action objected to the specification on the basis that the incorporation of essential material in the specification by reference to a foreign patent or publication is improper. The only subject matter incorporated by reference is Thornberry et al. at page 4, lines 10-13 of the application. The incorporated subject matter is not essential material, as defined in MPEP § 608.01(p)(I)(A), in that the incorporated subject matter is not necessary to describe the claimed invention, provide an enabling disclosure of the claimed invention, or describe the best mode. Instead, the subject matter incorporated by reference is nonessential material referred to for the purposes of indicating the background of the invention or the state

of the art. Nonessential subject matter may properly be incorporated by reference to a publication. *See* MPEP § 608.01(p)(I)(A). Accordingly, this objection to the specification should be withdrawn.

The Action also objected to the specification as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the detailed description section of the application discloses that the center of the liner internal concave surface may be shifted laterally up to 8 mm and medially up to 4 mm, while the claims of the application recite lateral shifting up to 10 mm and medial shifting up to 8 mm. Additionally, the detailed description section discloses that the center axis of the liner internal concave surface may be anteverted up to about 20 degrees, while the claims recite anteverting up to about 45 degrees. The detailed description section of the specification has been amended above to provide the proper antecedent basis for the claims. No new matter has been added because the amended subject matter was disclosed in the originally-filed claims.

An amendment adding a benefit claim to a provisional application is included above to comply with recently promulgated PTO rules regarding claiming the benefit of a prior-filed application under 35 U.S.C. § 119(e). The claim of benefit of the provisional application was made in an inventor declaration filed June 4, 2001 and has previously been recognized by the PTO as indicated by the updated filing receipt mailed July 14, 2001. Accordingly, Assignee believes that no fee or petition is necessary for entry of this amendment. If the Examiner disagrees, it is requested that he please contact the undersigned at his earliest convenience.

**Rejections of Claims 107-110 under 35 U.S.C. §§ 112 and 101**

The Action rejected claims 107-110 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Action asserts that claims 107 and 108 are ambiguous and therefore indefinite as to whether applicant is claiming a product or a process. Similarly, claims 107-110 were rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The Action asserts that claims 107-110 are directed to neither a process nor a machine but rather embrace or overlap two different statutory classes of invention.

Claims 107-110 depend from independent claim 102, which is directed to a prosthetic device, and further define the prosthetic device recited in claim 102. Accordingly, it is clear that claims 107-110 are directed to a single class of statutory subject matter, and the rejection of claims 107-110 under 35 U.S.C. § 101 should be withdrawn.

Similarly, claims 107-110 are not indefinite under 35 U.S.C. § 112. Claims 107 and 108 further define the prosthetic device of claim 102. Claim 102 includes several limitations defining the shape and structure of a sculpted surface of an acetabular liner of the prosthetic device. Within those limitations in claim 102, the use of “at least one femoral component” is recited in defining the sculpted surface. Claim 107 narrows these limitations to “one femoral component,” and claim 108 narrows these limitations to “a plurality of femoral components.” Thus, claims 107 and 108 are not ambiguous when read in the context of claim 102 from which they depend. Furthermore, the use of the “wherein” clause in claims 107 and 108, in contrast to the use of “further comprising” (e.g., such as in claim 143), clearly shows that

claims 107 and 108 are not reciting a femoral component as a further required component of the prosthetic device of claim 102. Accordingly, claims 107-110 are not indefinite, and the rejection of claims 107-110 under 35 U.S.C. § 112 should be withdrawn.

**Rejections of Claims 102-106, 117-124, 126-130, 135, 138, 139, and 143  
under 35 U.S.C. § 102(b)**

As noted above, claims 102-110, 116-130, 135, 138, 139, and 143 are now pending in the application. The Action rejects claims 102-106, 117-124, 126-130, 135, 138, 139, and 143 under 35 U.S.C. § 102(b). The Action rejects claims 102-106, 135, 138, 139, and 143 as anticipated by *The Effects of Neck Geometry and Acetabular Design on the Motion to Impingement in Total Hip Replacement* by Thornberry et al. (“*Thornberry*”). The Action rejects claims 102 and 117-124 as anticipated by *Reflection<sup>®</sup> Lateralized Liners* by Smith & Nephew (“*S&N*”). Finally, the Action rejects claims 102 and 126-130 as anticipated by U.S. Patent No. 5,507,824 to *Lennox* (“*Lennox*”).

Before discussing each of the references cited in the Action, the Examiner notes that “the products of the prior art cited below have the same **structural** limitations as those claimed” (emphasis in original). Because there is no further explanation of this statement, Assignee is unsure of what the Examiner is trying to convey by this statement, except possibly that the Examiner believes some of the claims include process limitations and that such limitations have not been considered by the Examiner in formulating the § 102 and § 103 rejections set forth in the Action. However, the Examiner has erred in taking this

position because the limitations of the claims are structural, and thus such limitations should be considered before applying any art to reject the pending claims.

For example, independent claim 102 recites:

A prosthetic device comprising:

(a) an acetabular shell comprising an internal concave surface adapted to receive a liner and an external surface adapted to be received in an acetabulum; and

(b) an acetabular liner having:

an internal concave surface adapted to receive the head of a femoral component;

an external surface positioned on an opposing side of the liner from the internal concave surface and adapted to be received in the internal concave surface of the acetabular shell;

a sculpted surface generally defining at least part of a rim of the liner, said surface located between the internal concave surface and an external surface of the liner; and

wherein the sculpted surface is defined at least in part by, given a desired angular position of the liner in a patient:

the impingement angle, at each of a plurality of radial locations around the rim, of at least one femoral component whose head is adapted to be received in the internal concave surface of the liner and which femoral component is disposed to permit the desired limit of range of motion at a corresponding radial location on said rim;

said impingement angle measured relative to a reference line defined by structure of the liner; and

wherein the shape of the sculpted surface varies around the rim of the liner in a manner corresponding to the cross-sectional shape of the portion of the at least one femoral component that is in an impingement condition with the liner.

In applying the cited art to claim 102, the Examiner appears not to have considered any of the underlined language. However, the underlined limitations are clearly structural limitations in that they define the shape and structure of the sculpted surface of the acetabular liner of the prosthetic device. Thus, the Examiner should have considered these limitations before applying the cited art to reject claim 102.

Furthermore, even if the limitations not considered by the Examiner in rejecting claim 102 are process limitations, the Examiner should have considered these limitations in assessing the patentability of claim 102 over the cited art. As stated in MPEP § 2113 (Ed. 8, Rev. 1, Feb. 2003):

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.) (emphasis added)

Thus, if the Examiner considers the underlined language of claim 102 to be manufacturing process steps rather than structural limitations, the Examiner is required to consider structure implied by the process steps where the steps would be expected to impart distinctive structural characteristics to the final product. There is no question that the underlined language of claim 102, whether considered as structural limitations or process limitations, is directed to distinctive structural characteristics of the sculpted surface of the acetabular liner. The Examiner failed to properly consider the structure implied by the limitations of the underlined language of claim 102. Accordingly, the Examiner erred in not considering each and every limitation of claim 102 before applying the cited art to reject claim 102.

Considering claim 102 in its entirety, claim 102 is allowable over *Thornberry*, *S&N*, and *Lennox*. Each of these references discloses an acetabular shell and an acetabular liner, as well as some additional, commonly employed structural parameters of acetabular liners, such

as anteversion of 20 degrees relative to the acetabular shell or shifting of the central axis of the acetabular liner laterally or medially about 4 mm. However, none of the references, alone or in combination, teach or suggest the sculpted surface of the acetabular liner as recited by claim 102. Accordingly, for at least the above reasons, the rejections of claim 102 under 35 U.S.C. § 102(b) should be withdrawn, and claim 102 should be allowed.

Each of claims 103-110, 117-124, 126-130, 135, 138, 139, and 143 ultimately depends from independent claim 102. Inasmuch as claims 103-110, 117-124, 126-130, 135, 138, 139, and 143 depend from and thereby include the limitations of claim 102, claims 103-110, 117-124, 126-130, 135, 138, 139, and 143 should also be allowed, for at least such dependencies.

**Rejection of Claims 102, 122, and 125 under 35 U.S.C. § 103(a)**

The Action rejects claims 102, 122, and 125 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,879,404 to *Bateman et al.* ("*Bateman*"). Similar to the references discussed above, *Bateman* does not teach or suggest each and every limitation of claim 102, including at least those limitations that the Examiner failed to consider in applying *Bateman* to reject claims 102, 122, and 125. For at least the above reasons, the Examiner should withdraw the rejection of claims 102, 122, and 125 under 35 U.S.C. § 103(a), and claims 101, 122, and 125 should be allowed.

**Claims 107-110 and 116**

Claim 116 was not addressed by the Action, and, as noted above, the § 101 and § 112 rejections of claims 107-110 should be withdrawn. Accordingly, claims 107-110 and 116 should be allowed.




CONCLUSION

The foregoing is submitted as a full and complete response to the Office Action mailed July 1, 2003. Assignee submits that claims 102-110, 116-130, 135, 138, 139, and 143 are allowable for at least the reasons set forth above, and allowance of these claims is respectfully requested.

Other than the \$180 fee required for the supplemental information disclosure statement submitted herewith, no fees are believed due at this time. Nevertheless, the Commissioner is authorized to charge any additional fees that may be due for this Response, or credit any overpayment, to Deposit Account No. 11-0855.

Respectfully submitted,



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